



29 January 2016  
EMA/67219/2016  
Press office

## Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures

Adopted at the CHMP meeting of 25-28 January 2016

**Table 1.** Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Glybera</b> , (alipogene tiparvovec), uniQure biopharma B.V.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>IMVANEX</b> , (modified vaccinia ankara virus), Bavarian Nordic A/S,	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Orphacol</b> , (cholic acid), LABORATOIRES CTRS - BOULOGNE BILLANCOURT	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Vedrop</b> , (tocofersolan), Orphan Europe S.A.R.L.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances

**Table 2.** Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Deltyba</b> , (delamanid), Otsuka Novel Products	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
<b>Pixuvri</b> , (pixantrone), CTI Life Sciences Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Zykadia</b> , (ceritinib), Novartis Europharm Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

**Table 3.** Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Trajenta</b> , (linagliptin), Boehringer Ingelheim International GmbH	Positive Opinion	Unlimited validity
<b>XGEVA</b> , (denosumab), Amgen Europe B.V.	Positive Opinion	Unlimited validity

**Table 4.** Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Masitinib mesylate	treatment of smouldering or indolent systemic mastocytosis with severe handicaps		X
Tenofovir alafenamide	treatment of chronic hepatitis B in adults		X
Olaratumab	indicated in combination with doxorubicin for the treatment of adult patients with advanced or metastatic soft tissue sarcoma (STS) who are not amenable to curative treatment with surgery or radiotherapy	X	